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Guideline

## **Tokyo Guidelines 2018 management bundles for acute cholangitis and cholecystitis**

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## **Abstract**

Management bundles that define items or procedures strongly recommended in clinical practice have been used in many guidelines in recent years. Application of these bundles facilitates the adaptation of guidelines and helps improve the prognosis of target diseases. In Tokyo Guidelines 2013 (TG13), we proposed management bundles for acute cholangitis and cholecystitis. Here, in Tokyo Guidelines 2018 (TG18), we redefine the management bundles for acute cholangitis and cholecystitis. Critical parts of the bundles in TG18 include the diagnostic process, severity assessment, transfer of patients if necessary, and therapeutic approach at each time point. Observance of these items and procedures should improve the prognosis of acute cholangitis and cholecystitis. Studies are now needed to evaluate the dissemination of these TG18 bundles and their effectiveness.

## **Introduction**

Detailed guidelines are now being released in many fields of medicine, and it is not easy for clinical physicians to keep all of the contents of these guidelines in mind when treating patients. Nevertheless, to improve patient prognosis, such guidelines need to be widely disseminated and used in clinical practice. Using bundles in health care simplifies complex patient care processes. A bundle is a selected set of elements of care that are distilled from evidence-based practice guidelines and that, when implemented as a group, have an effect on outcomes beyond that achieved when the individual elements are implemented alone.

We proposed management bundles for acute cholangitis and cholecystitis in Tokyo Guidelines 2013 (TG13) [1]. Here, as part of TG18, we propose a new flowchart for the treatment of acute cholecystitis and have made several changes to the clinical practice guidelines for managing acute cholangitis and acute cholecystitis.

## **Efficacy of the bundles**

A good example for the effectiveness of using bundles is the sepsis bundles in the Surviving Sepsis Campaign Guidelines. Sepsis bundles were introduced in 2008, and improvements in compliance and survival with the bundles were investigated in a number of studies [2]- [6]. These reports showed a marked reduction in hospital mortality rates in patients whose care included compliance with most of the bundles.

To encourage adherence to clinical guidelines and improve care processes, the Institute for Healthcare Improvement developed the concept of “care bundles” [7] in critical care patients. Various strategies such as education (86%), reminders (71%), and audit and feedback (63%) have been used to encourage the implementation of the care bundles in intensive care units ([8], 26276569).

As with TG13, in the process of developing TG18, mandatory items or procedures to be included in the management bundles have been discussed and defined among Tokyo Guidelines Revision Committee members. On the basis of the recommendations in TG18, those items that are expected to yield favorable treatment results have been included in the bundles to assure the appropriate interventions for acute cholangitis and cholecystitis at the appropriate times. The TG13 checklists also have been updated to confirm compliance with the bundles.

### **Acute cholangitis management bundle (Table 1)**

Few changes have been made in the TG18 management bundle for acute cholangitis compared with the TG13 one, with the exception of the addition of recommendations for patient transfer [9]. If acute cholangitis is suspected, perform a diagnostic assessment by using the TG18 diagnostic criteria [10]. If a definitive diagnosis cannot be made, reassess the patient every 6 to 12 h using the diagnostic criteria. Use the severity assessment criteria [9] to assess severity repeatedly: at diagnosis, within 24 h after diagnosis, and again during the next 24 to 48 h. Provide initial treatment, such as sufficient fluid replacement, electrolyte compensation, and intravenous administration of analgesics and full-dose antimicrobial agents, as soon as a diagnosis has been made [11]. Perform biliary drainage, and culture the blood or bile, or both, if the condition is sufficiently severe [12]. If the hospital is not equipped to

perform endoscopic or percutaneous transhepatic biliary drainage or to provide intensive care, transfer patients with moderate or severe cholangitis to a hospital that is capable of providing these treatments.

### **Acute cholecystitis management bundle (Table 2)**

If acute cholecystitis is suspected, diagnostic assessment is made by using the TG18 diagnostic criteria [13]. If a definite diagnosis cannot be made, reassess the patient every 6 to 12 h using the diagnostic criteria. Use the severity assessment criteria [13] to assess the severity repeatedly: at diagnosis, within 24 h after diagnosis, and again at 24 to 48 h, and evaluate the surgical risk (e.g. presence of local inflammation, Charlson comorbidity index, American Society of Anesthesiologists physical status classification, or the predictive factors). Taking into consideration the need for cholecystectomy, as soon as a diagnosis has been made, initiate treatment, including sufficient fluid replacement, electrolyte compensation, fasting, and administration of intravenous analgesics and full-dose antimicrobial agents [11,13]. Urgent or early laparoscopic cholecystectomy (Lap-C), urgent or early biliary drainage, and blood or bile culture (or both) should be performed according to the severity and surgical risk [14-17]. Consider transferring the patient to advanced facilities if facilities for urgent or emergency Lap-C, biliary drainage, and intensive care are not available [14].

### **Checklist for the use of management bundles for acute cholangitis and cholecystitis (Tables 3, 4)**

Checklists are given to ensure effective use of the bundles. Use of these lists in medical care ensures that standards are maintained and is thought to improve the effectiveness of the bundles. The TG13 checklists also have been updated to confirm compliance with the bundles [1]. A checklist of the procedures, laboratory tests, monitoring, and interventions required should be placed at the patient's bedside.

## Conclusions

Bundles consist of important items and procedures for the effective application of TG18. Reports from various facilities have demonstrated that improved prognosis can be expected through the use of the Tokyo Guidelines for acute cholangitis and cholecystitis.

Future evaluations of the distribution of TG18 bundles and of changes in prognosis will provide evidence for the future construction and revision of TG18.

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**Conflicts of interest:** None

## Appendix

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**Table 1 Management bundle for acute cholangitis**

1. When acute cholangitis is suspected, perform a diagnostic assessment every 6 to 12 h using TG18 diagnostic criteria until a diagnosis is reached ..
2. Perform abdominal US, followed by a CT scan, MRI, MRCP, and HIDA scan as required.
3. Use the severity assessment criteria to assess severity repeatedly: at diagnosis, within 24 h after diagnosis, and from 24 to 48 h after diagnosis.
4. As soon as a diagnosis has been made, provide initial treatment. The treatment is as follows:  
sufficient fluid replacement, electrolyte compensation, and intravenous administration of analgesics and full-dose antimicrobial agents.
5. In patients with Grade I (mild) disease, if no response to the initial treatment is observed within 24 h, perform biliary tract drainage immediately.
6. In patients with Grade II (moderate) disease, perform biliary tract drainage immediately along with the initial treatment. If early drainage cannot be performed because of a lack of facilities or skilled personnel, consider transferring the patient.
7. In patients with Grade III (severe) disease, perform urgent biliary tract drainage along with the initial treatment and give general supportive care. If urgent drainage cannot be performed because of a lack of facilities or skilled personnel, consider transferring the patient.
8. In patients with Grade III (severe) disease, supply organ support (e.g. noninvasive/invasive positive pressure ventilation, use of vasopressors and antimicrobial agents) immediately.
9. Perform blood culture or bile culture, or both, in Grade II (moderate) and III (severe) patients.
10. Consider treating the etiology of acute cholangitis with endoscopic, percutaneous, or operative intervention once the acute illness has resolved. Cholecystectomy should be performed for cholecystolithiasis after the acute cholangitis has resolved.

11. If the hospital is not equipped to perform endoscopic or percutaneous transhepatic biliary drainage or provide intensive care, transfer patient with moderate or severe cholangitis to a hospital capable of providing these treatments.
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US, ultrasonography; CT, computed tomography; MRI, magnetic resonance imaging; MRCP, magnetic resonance cholangiopancreatography; HIDA, hepatobiliary iminodiacetic acid

**Table 2 Management bundle for acute cholecystitis**

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1. When acute cholecystitis is suspected, perform a diagnostic assessment every 6 to 12 h using TG18 diagnostic criteria until a diagnosis is reached .
  2. Perform abdominal US, followed by a CT scan or HIDA scan if needed to make a diagnosis.
  3. Use the severity assessment criteria to assess severity repeatedly: at diagnosis, within 24 h after diagnosis, and from 24 to 48 h after diagnosis. Evaluate the surgical risk (e.g. local inflammation, CCI, ASA, PS, predictive factors).
  4. Taking into consideration the need for cholecystectomy, as soon as a diagnosis has been made, initiate treatment, with sufficient fluid replacement, electrolyte compensation, fasting, and administration of intravenous analgesics and full-dose antimicrobial agents.
  5. In Grade I (mild) patients, laparoscopic cholecystectomy (Lap-C) at an early stage, i.e. within 7 days (within 72 h is better) of onset of symptoms is recommended.
  6. If conservative treatment is selected for patients with Grade I (mild) disease and no response to initial treatment is observed within 24 h, reconsider early Lap-C if patient performance status is good and fewer than 7 days have passed since symptom onset or biliary tract drainage.
  7. In Grade II (moderate) patients, consider urgent/early Lap-C if patient performance status is good and the advanced Lap-C technique is available. If the patient's condition is poor, urgent/early biliary drainage, or delayed/elective Lap-C, can be selected.
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8. In Grade III (severe) patients with high surgical risk\*, perform urgent/early biliary drainage. If there are neither negative predictive factors\*\* nor FOSF\*\*\* and the patient has good PS, early Lap-C at an advanced center can be chosen.
9. Perform blood culture or bile culture, or both, in Grade II (moderate) and III (severe) patients.
10. Consider transferring the patient to advanced facilities if urgent/emergency Lap-C, biliary drainage, and intensive care are not available.
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US, ultrasonography; CT, computed tomography; HIDA, hepatobiliary iminodiacetic acid; CCI; Charlson Comorbidity Index; ASA, American Society of Anesthesiologists class; PS, performance status

\*high surgical risk: evaluate CCI, ASA, PS, predictive factors, and FOSF

\*\*predictive factors: jaundice (T-Bil  $\geq 2$ ), neurological dysfunction, respiratory dysfunction

\*\*\*FOSF: favorable organ system failure = cardiovascular or renal organ system failure that is rapidly reversible after admission and before early Lap-C in acute cholecystitis

**Table 3 Acute cholangitis bundle checklist**

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- ☐ Repeat the diagnosis every 6 to 12 h
  - ☐ Perform diagnostic imaging: abdominal US followed by CT scan, MRI, MRCP, and HIDA scan as needed.
  - ☐ Assess severity at diagnosis, within 24 h; and from 24 to 48 h after diagnosis..
  - ☐ After diagnosis, immediately start antibiotic administration and general supportive care.
  - ☐ Grade I (mild): perform biliary drainage when no symptom improvement is observed within 24 h.
  - ☐ Grade II (moderate): perform biliary drainage immediately.
  - ☐ Grade III (severe): apply organ support and emergency biliary drainage.
  - ☐ Consider transfer when the above procedures are unavailable.
  - ☐ Grade II (moderate) and III (severe): culture blood or bile or both.
  - ☐ Consider surgical procedures to remove causes after biliary drainage and amelioration of organ failure.
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**Table 4 Acute cholecystitis bundle checklist**

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- ☐ Repeat the diagnosis every 6 to 12 h.
  - ☐ Perform diagnostic imaging: US, followed by CT and HIDA scan
  - ☐ Assess severity at diagnosis and within 24 h after diagnosis; repeat severity assessment every 24 h and evaluate surgical risk.
  - ☐ Immediately initiate antibiotic administration and general supportive care.
  - ☐ Grade I (mild): perform laparoscopic cholecystectomy (Lap-C) at an early stage within 7 days (within 72 h is better) of onset of symptoms.
  - ☐ Conservative treatment for Grade I (mild): if condition is worsening or no improvement is observed within 24 h, reconsider early Lap-C if fewer than 7 days since biliary drainage (cholecystostomy).
  - ☐ Grade II (moderate): perform urgent/early Lap-C if patient performance status is good and advanced Lap-C technique is available. If not, urgent/early biliary drainage or delayed/elective Lap-C can be selected.
  - ☐ Grade III (severe): perform urgent/early biliary drainage in patients with high surgical risk. If there are neither negative predictive factors nor FOSF and the patient has a good PS, early Lap-C at an advanced center can be chosen.
  - ☐ Grade II (moderate) and III (severe): culture blood or bile or both.
  - ☐ Consider transferring the patient to advanced facilities if urgent/emergency Lap-C, biliary drainage, and intensive care are not available.
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